From:	Larry Brewer
To:	Bill Jacobs/DC/USEPA/US@EPA
Subject:	RE: Standard House Mouse Acute Placepack Penetration guideline revised 7/28/91
Date:	02/24/2010 11:00 AM

Bill,
Thank you for your thorough response. It answers all my questions.

Best regards,

Larry

Larry Brewer
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Springborn Smithers Laboratories
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-----Original Message-----
From: Jacobs.Bill@epamail.epa.gov [mailto:Jacobs.Bill@epamail.epa.gov]
Sent: Wednesday, February 24, 2010 7:46 AM
To: Larry Brewer
Subject: Re: Standard House Mouse Acute Placepack Penetration guideline revised 7/28/91

It appears as though I made some copy-and-paste errors with this Protocol 1.220 when I updated it. As it has been used almost not at all since then, no one has brought the problems to my attention until just now.

The exposure period for acute rodenticide baits in choice-feeding trials (e.g. Protocol 1.210) was shortened from 3 days to 2 days when they were revised. (The 3-day period originally was used because the protocols were developed for market surveillance testing, and we wanted to give collected products ample chance not to be judged deficient. When that program was dropped, the main purpose for the protocols was for assessing the efficacy of fresh baits as prepared by their manufacturers. As it turned out, all acute toxicants on the market in the early 1990's were capable of performing to criterion if the carrier was palatable to rodents.) The 5-day post-exposure period was standard for all of our laboratory efficacy tests until we made adaptations for testing the so-called single-feeding anticoagulants so that the exposure period would be shortened but ample time would be allowed for animals to die or recover on time courses typical for anticoagulants. Hence, we wrote options for longer post-treatment observation periods into the "acute" methods that also could be used to assess "single-feeding anticoagulants".

If the product that you are planning to test contains an acute rodenticide as the active ingredient, use a bait-exposure of 2 or 3 days (due to the confusion, we should take either at this point) and include a 5-day, post-exposure monitoring period. So, the test duration would be 7-8 days. If you are testing an anticoagulant in placepacks, use Protocol 1.218. Qualification for the "single-night's feeding" claim would have to be established through testing the bait in a choice trial via Protocol 1.210, as modified for testing anticoagulant baits, so it would not have to be re-established in the placepack test.

The pre-test business has to do with how long the animals must be in the test facility before the bait-exposure period starts (7 days) and how long they must be in the specific cages (under test conditions) in which the bait-exposure trials are to be run (3 days). When I get back, I'll have to check Protocol 1.220 to see whether it also confuses me on those points.

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|"Larry Brewer" <lbrewer@springbornsmithers.com>
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| To: |
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|Bill Jacobs/DC/USEPA/US@EPA
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| Date: |
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|02/23/2010 06:57 PM
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| Subject: |
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|Standard House Mouse Acute Placepack Penetration guideline revised 7/28/91
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Dear Bill,

I am reviewing OPP Protocol 1.220 "Standard House Mouse Acute Place Pack Dry Bait Laboratory Test Method" and have encountered what appear to be contradictions between different sections of the protocol. I'm hoping you can provide clarity for me on a couple of these issues.

In Section 5.1 the protocol specifies that for 7 days immediately prior to exposure, the test animals must be maintained under study conditions. Then, in Section 7.0, it states that for 3 days prior to exposure the test animals will be maintained in study room conditions. Can you please clarify whether this should be 7 days or 3 days?

In Section 8.1 the protocol states "maintain the test period for 3 days ", which is a logical exposure period for an acute bait. In the same section, next sentence, it states "…, monitoring of control-group animals must continue for the 15-day test period plus the full follow-up period. Then, in Section 9.1 it states "maintain observation of test- and control-group mice for a minimum of 5 days following test period." For an acute bait is the test period 3 days or 15 days or 3 days plus 15 days? A test period of 3 days and a follow-up period of 5 days seems logical for an acute bait efficacy test. However, a test period for surviving test- and control-group animals of 18 days (3 plus 15), plus a 5-day follow-up period in combination (20 days of observation after 3 days of exposure)would be reasonable for an anti-coagulant bait, but seems to me to be unreasonably long for an acute bait test. Is it possible that the mention of 15-day test period is an unintentional hold-over from the anti-coagulant test protocol?

I would appreciate any guidance you can provide regarding these questions.

Sincerely.

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